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चिकित्सीय वस्त्रादि — हाइड्रोकोलॉइड  
मरहम पट्टियां — विशिष्टि

Medical Textiles — Hydrocolloid  
Dressing — Specification

ICS 11.040.30; 59.080.01

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## FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Hydrocolloid dressings are conformable dressing for partial and full thickness dermal ulcers, superficial wounds, abrasions, first and second-degree burns, and donor sites with a barrier to liquid, bacteria and virus. It may also be used as a protective dressing on at-risk, undamaged skin or on skin beginning to show signs of damage from friction or shear.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## *Indian Standard*

# MEDICAL TEXTILES — HYDROCOLLOID DRESSING — SPECIFICATION

## 1 SCOPE

This standard specifies requirements for hydrocolloid dressing with or without non-adherent absorbent pad intended for medical use.

This standard does not cover the drug component applied/coated on the product.

## 2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

## 3 TERMS AND DEFINITIONS

For the purposes of this standard, the following term shall apply:

**3.1 Biocompatibility** — The ability to be in contact with a living system without producing an adverse effect.

**3.2 Hydrocolloid Dressing** — A sterile flexible dressing made of an adhesive and hydrocolloid material with a water-resistant film. Dressing may be supplied with or without antimicrobial agents.

**3.3 Manufacturer** — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

**3.4 Water Vapour Permeability** — Permeability of materials to the passage of water molecules from the skin contact side to the external atmosphere under controlled conditions of humidity and temperature.

## 4 WORKMANSHIP AND FINISH

**4.1** A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

**4.2** The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

**4.3** During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

## 5 GENERAL REQUIREMENTS

**5.1** The hydrocolloid dressing shall be made from suitable material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard.

**5.2** The manufacturer shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labeling, distribution and provision of related services as per Medical Device Rules, 2017 for hydrocolloid dressing. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

**5.3** Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging (as per IS/ISO 11607 Part 1 and Part 2), validation (as per IS/ISO 11137 Part 1 and 2, ISO 11138 Part 7) and residual sterility (IS/ISO 10993 Part 7) shall be maintained by the manufacture.

## 6 REQUIREMENTS

**6.1** The hydrocolloid dressing shall conform to the requirements specified in Table 1

## 7 MARKING

**7.1** Each piece of the hydrocolloid dressings shall be legibly marked with the following information:

- a) Name of the product;
- b) Manufacturer's name, initials or trade-mark, if any;
- c) Month and year of manufacture;

- d) Batch/Lot No.;
- e) Size;
- f) Labelling and marking requirements shall be followed as per Medical Device Rules 2017; and
- g) Any other statutory requirement as required by the law in force.

## 7.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

## 8 SAMPLING AND CRITERIA FOR CONFORMITY

### 8.1 Lot

All the hydrocolloid dressings of the same material and dimensions produced under similar conditions of manufacture within a single sterilization batch shall constitute a lot.

**8.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot.

**8.1.2** The number of hydrocolloid dressings to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 2.

**8.1.3** These hydrocolloid dressings shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

### 8.2 Number of Tests and Criteria for Conformity

**8.2.1** All the selected hydrocolloid dressings as per column 3 of Table 2 shall be examined for workmanship and finish (*see 4.1 to 4.3*).

**8.2.1.1** Any hydrocolloid dressings failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

**Table 1 Performance Requirements for Hydrocolloid Dressing**

( Clause 6.1 )

| Sl No. | Characteristics                      | Requirement                                    | Method of Test, Ref to |
|--------|--------------------------------------|------------------------------------------------|------------------------|
| (1)    | (2)                                  | (3)                                            | (4)                    |
| i)     | Waterproofness                       | Complies with test                             | IS 14944               |
| ii)    | Extensibility                        | Complies                                       | IS 14944               |
| iii)   | Water vapour permeability            | Not less than 1 g/10 cm <sup>2</sup> /24 hours | IS 14944               |
| iv)    | Absorbency                           | Complies                                       | Annex B                |
| v)     | Biocompatibility evaluation**        |                                                |                        |
|        | a) Cytotoxicity                      | None                                           | IS/ISO 10993-5         |
|        | b) Irritation and skin sensitization | Non-irritant and Non-sensitizer                | IS/ISO 10993-10        |

\*\*Remarks: Confirm the biocompatibility of raw material at designed stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

**Table 2 Number of Hydrocolloid Dressing to be Selected**

( Clauses 8.1.2, 8.2.1, 8.2.1.1, 8.2.2 and 8.2.3 )

| Sl No. | Lot Size       | Non-Destructive Testing         |                   | Destructive Testing             |                       |
|--------|----------------|---------------------------------|-------------------|---------------------------------|-----------------------|
|        |                | No. of Dressings to be Selected | Acceptance Number | No. of Dressings to be Selected | Acceptance Number     |
|        | <i>N</i>       | <i>n</i>                        | <i>a</i>          | <i>n</i> <sub>1</sub>           | <i>a</i> <sub>1</sub> |
| (1)    | (2)            | (3)                             | (4)               | (5)                             | (6)                   |
| i)     | Up to 280      | 13 <sup>1)</sup>                | 1                 | 8                               | 0                     |
| ii)    | 281 - 500      | 20                              | 2                 | 8                               | 0                     |
| iii)   | 501 - 1 200    | 32                              | 3                 | 13                              | 0                     |
| iv)    | 1 201 - 3 200  | 50                              | 5                 | 13                              | 0                     |
| v)     | 3 201 - 10 000 | 80                              | 7                 | 20                              | 1                     |

<sup>1)</sup> Or lot size when less than 13.

**8.2.2** Out of the sample already found satisfactory according to **8.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

**8.2.3** The lot shall be considered as conforming to the requirements of the specification if the total number of defective dressing found in the sample (as per **8.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 2.

## **9 PACKAGING AND STERILIZATION**

**9.1** For packaging of the products, requirements as per IS/ISO 11607-1 and 2 shall be followed.

For packaging and sterilization, the Medical Device Rule 2017 shall be followed.

**9.2** Validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7 and, IS/ISO 10993-7.

## ANNEX A

( Clause 2 )

## LIST OF REFERRED INDIAN STANDARDS

| <i>IS/Other<br/>Publication</i> | <i>Title</i>                                                                                                                                                          | <i>IS/Other<br/>Publication</i> | <i>Title</i>                                                                                                                                                             |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4905 : 2015                     | Random sampling and randomization procedures<br>(first revision)                                                                                                      | IS/ISO 11137-2 : 2013           | Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose                                                                            |
| 14944 : 2001                    | Surgical dressings — Methods of test                                                                                                                                  | IS/ISO 11135 : 2014             | Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices |
| IS/ISO 10993-5 : 2009           | Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity                                                                                      | ISO 11138-7 : 2019              | Sterilization of health care products—Biological indicators— Part 7: Guidance for the selection, use and interpretation of results                                       |
| IS/ISO 10993-7 : 2008           | Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals                                                                               | ISO 11737-1 : 2018              | Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products                                    |
| IS/ISO 10993-10 : 2010          | Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization                                                                         | ISO 14698-1 : 2003              | Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and Methods                                                    |
| IS/ISO 11607-1 : 2006           | Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems                                 | ISO 14644-1 : 2015              | Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration                                                  |
| IS/ISO 11607-2 : 2006           | Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes                                       |                                 |                                                                                                                                                                          |
| IS/ISO 11137-1 : 2006           | Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices |                                 |                                                                                                                                                                          |

**ANNEX B***( Foreword )***COMMITTEE COMPOSITION**

Technical Textiles for Medtech Applications, TXD 36

| <i>Organization</i>                                                | <i>Representative(s)</i>                                               |
|--------------------------------------------------------------------|------------------------------------------------------------------------|
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This Indian Standard has been developed from Doc No.: TXD 36 (15156).

### Amendments Issued Since Publication

| Amend No. | Date of Issue | Text Affected |
|-----------|---------------|---------------|
|           |               |               |
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Published by BIS, New Delhi